

Customer No.: 07278



Docket No.: 04266/100M192-US4

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of: Amedeo LEONARDI et al.

Serial No.: 10/688,061

Art Unit: T.B.A.

Filed: October 16, 2003

Examiner: T.B.A.

For: **LISINOPRIL/LERCANIDIPINE COMBINATION THERAPY**

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**INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

Sir:

In order to comply with 37 CFR 1.97 and 1.98, attached hereto is a copy of form PTO/SB/08a/b and copies of citations no. 21-54 listed thereon. Each of citations no. 1-20 listed on the form PTO/SB/08a/b is a U.S. patent or U.S. patent application publication. The Patent and Trademark Office has waived the requirement under 37 CFR 1.98(a)(2)(i) for submitting a copy of each cited U.S. patent and each cited U.S. patent application publication for all U.S. national patent applications filed after June 30, 2003. Official Gazette, August 5, 2003. The subject application was filed on October 16, 2003. Copies of citations no. 1-20 on the accompanying PTO/SB/08a/b are therefore not required and are not enclosed, accordingly.

In accordance with MPEP Sections 609 and 707.05(b), it is requested that each document cited (including any cited in applicant's specification which is not repeated on the attached form PTO/SB/08a/b) be given thorough consideration and that it be cited of record in the prosecution history of the present application by initialing form PTO/SB/08a/b next to the document. Such initialing is requested even if the Examiner does not consider a cited document to be sufficiently pertinent to use in a rejection, or otherwise does not consider it to be prior art for any reason, or even if the Examiner does not believe that the guidelines for citation have been

fully complied with. This is requested so that each document becomes listed on the face of the patent issuing on the present application.

Certain documents cited on form PTO/SB/08a/b are not in the English language. Each such document not in the English language is accompanied by an English-language abstract. Thus, the requirement for a concise explanation of the relevance of each document not in the English language is believed to be satisfied. MPEP 609 III(A)(3).

This submission is filed before a first action on the merits has been mailed.

The present Information Disclosure Statement is being submitted in compliance with 37 CFR 1.56, but the citation of such document is not to be construed as an admission that such document is necessarily relevant or prior art. No representation is intended that the cited documents represent the results of a complete search, and it is anticipated that the Examiner, in the normal course of examination, will make an independent search and will determine the best prior art consistent with 37 CFR 1.104(a) and in the course of each search, will review for relevance every document cited on the attached form even if not initialed.

It is believed that no fee is due. However, if the Commissioner determines that a fee is due, the Commissioner is hereby authorized to charge Deposit Account No. 04-0100 for any deficiency.

Early and favorable consideration is earnestly solicited.

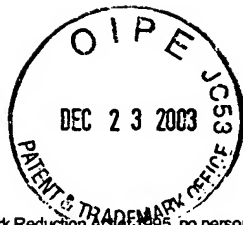
Respectfully submitted,



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Dated: December 23, 2003

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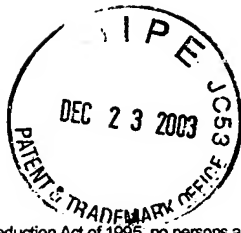
<b>Substitute for form 1449/PTO</b>  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)			<b>Complete if Known</b>		
			Application Number	10/688,061	
			Filing Date	October 16, 2003	
			First Named Inventor	Amedeo LEONARDI, et al.	
			Art Unit		
Examiner Name	TBA				
Attorney Docket Number	04266/100M192-US4				
Sheet	1	of	3		

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
	1.	US 4,294,832	10-13-1981	Yoneda et al.	
	2.	US 4,344,949	08-17-1982	Hoefle et al.	
	3.	US 4,350,633	09-21-1982	Kim et al.	
	4.	US 4,350,704	09-21-1982	Hoefle et al.	
	5.	US 4,555,502	11-26-1985	Patchett et al.	
	6.	US 4,705,797	11-10-1987	Nardi et al.	
	7.	US 4,772,621	09-20-1988	Nardi et al.	
	8.	US 4,931,430	06-05-1990	Sudilovsky et al.	
	9.	US 4,931,464	06-05-1990	Grover et al.	
	10.	US 4,968,832	11-06-1990	Nardi et al.	
	11.	US 5,037,821	08-06-1991	Horovitz	
	12.	US 5,098,910	03-24-1992	Becker et al.	
	13.	US 5,696,139	12-09-1997	Leonardi et al.	
	14.	US 5,767,136	06-16-1998	Sartani et al.	
	15.	US 5,912,351	06-15-1999	Leonardi et al.	
	16.	US 6,086,919	07-11-2000	Bauer et al.	
	17.	US 6,110,684	08-29-2000	Kemper et al.	
	18.	US 6,183,958	02-06-2001	Stanton Jr.	
	19.	US 6,200,754	03-13-2001	Housman et al.	
	20.	US 2003/0180355 A1	09-25-2003	Leonardi et al.	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	† <sup>6</sup>
		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)				
	21.	CA 2 070 085 ✓	12-01-1992	Polli		
	22.	DE 3 437 917 ✓	04-17-1986	Bayer AG		
	23.	DE 3 633 496 ✓	04-14-1988	Hoechst AG		
	24.	DE 3 736 505 ✓	05-05-1988	Sandoz-Patent-Gmbh		
	25.	DE 4 109 134 ✓	09-24-1992	Knoll AG		
	26.	DE 4 141 646	06-24-1993	Klinge Pharma mbh & Co KG		
	27.	DE 4 308 504 ✓	09-22-1994	Knoll AG		
	28.	EP 259 838 ✓	03-16-1988	Syntex (USA) Inc.		
	29.	EP 272 177	06-22-1988	Synthelabo		
	30.	EP 331 803	09-13-1989	Squibb ER & Sons Inc.		
	31.	EP 334 264 ✓	09-27-1989	Squibb ER & Sons Inc		
	32.	EP 344 995 ✓	12-06-1989	Squibb ER & Sons Inc		

Examiner Signature		Date Considered	
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\*EXAMINER: INITIAL IF REFERENCE CONSIDERED, WHETHER OR NOT CITATION IS IN CONFORMANCE WITH MPEP 609. DRAW LINE THROUGH CITATION IF NOT IN CONFORMANCE AND NOT CONSIDERED. INCLUDE COPY OF THIS FORM WITH NEXT COMMUNICATION TO APPLICANT. <sup>1</sup> APPLICANT'S UNIQUE CITATION DESIGNATION NUMBER (OPTIONAL). <sup>2</sup> SEE KINDS CODES OF USPTO PATENT DOCUMENTS AT [WWW.USPTO.GOV](http://WWW.USPTO.GOV) OR MPEP 901.04. <sup>3</sup> ENTER OFFICE THAT ISSUED THE DOCUMENT, BY THE TWO-LETTER CODE (WIPO STANDARD ST.3). <sup>4</sup> FOR JAPANESE PATENT DOCUMENTS, THE INDICATION OF THE YEAR OF THE REIGN OF THE EMPEROR MUST PRECEDE THE APPLICATION NUMBER OF THE PATENT DOCUMENT. <sup>5</sup> KIND OF DOCUMENT BY THE APPROPRIATE SYMBOLS AS INDICATED ON THE DOCUMENT UNDER WIPO STANDARD ST. 16 IF POSSIBLE. <sup>6</sup> APPLICANT IS TO PLACE A CHECK MARK HERE IF ENGLISH LANGUAGE TRANSLATION IS ATTACHED.



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Substitute for form 1449/PTO				<b>Complete if Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(use as many sheets as necessary)</i>				Application Number	10/688,061
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				First Named Inventor	Amedeo LEONARDI, et al.
				Art Unit	
				Examiner Name	TBA
Sheet	2	of	3	Attorney Docket Number	04266/100M192-US4

33.	EP 381 075 ✓	08-08-1990	Squibb ER & Sons Inc		
34.	EP 795 327 ✓	09-17-1997	Pfizer Inc		
35.	EP 884 054 ✓	12-16-1998	Vita-Invest SA		
36.	FR 2 733 911 ✓	11-15-1996	Takeda Chem Ind Ltd		
37.	WO 96/07400 ✓	03-14-1996	Astra AB		
38.	WO 98/45477	10-15-1998	Eurona Medical AB		
39.	WO 01/76632 ✓	10-18-2001	Wald and Law		
40.	WO 02/34303 ✓	05-02-2002	Nitromed, Inc.; Trustees of Boston Univ.		

NON PATENT LITERATURE DOCUMENTS					
Examiner Initials <sup>*</sup>	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.			T <sup>2</sup>
	41.	Aranda et al., (2000) "Therapeutic Efficacy and Tolerability of Lercanidipine Versus Candesartan, Alone or in Combination, in Mild-Moderate Essential Hypertensives", <i>Journal of Hypertension</i> , 18(suppl. 2):S152			
	42.	Cleophas et al., (2001) "Diabetics with Hypertension Not Controlled with ACE Inhibitors: Alternate Therapies", <i>Angiology</i> , 52:469-475			
	43.	Gasser et al., (1999) "Lercanidipine, a new third generation Ca-antagonist in the treatment of hypertension", <i>J Clin Basic Cardiol</i> , 2:169-174			
	44.	Grandi et al., (2002) "Aldosterone Antagonist Improves Diastolic Function in Essential Hypertension", <i>Hypertension</i> , 40:647-652			
	45.	Mancia et al., (1998) "Clinical Advantages of Lipophilic Dihydropyridines", <i>Blood Pressure</i> , 7(suppl 2):23-26			
	46.	Mancia and Grassi (1994) "Combination treatment of hypertension", <i>High Blood Pressure</i> , 3 (suppl to No. 4): 5-7			
	47.	McClellan and Jarvis (2000) "Lercanidipine: A Review of its Use in Hypertension", <i>Drugs</i> , 60:1123-1140			
	48.	Menard and Bellet (1993) "Calcium Antagonists-ACE Inhibitors Combination Therapy: Objectives and Methodology of Clinical Development", <i>J of Cardiovascular Pharmacology</i> , 21(suppl. 2):S49-S54			
	49.	Omboni and Zanchetti (1998) "Antihypertensive efficacy of lercanidipine at 2.5, 5 and 10mg in mild to moderate essential hypertensives assessed by clinic and ambulatory blood pressure measurements", <i>J Hypertens</i> , 16:1831-1838.			
	50.	Ramsay et al., (1999) "Guidelines for management of hypertension: report of the third working party of the British Hypertension Society", <i>J of Human Hypertension</i> , 13:569-592			

Examiner Signature		Date Considered	
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				Examiner Name	TBA
Sheet	3	of	3	Attorney Docket Number	04266/100M192-US4

51.	Recordati et al. (2000) "Effects of a reversible 'nephrectomy' on renal sympathetic activity and blood pressure in the rat: evidence for an acute angiotensin-mediated hypertension", <i>Journal of Hypertension</i> , 18:1277-1287	
52.	Rengo and Romis (1997) "Activity of Lercanidipine in Double-Blind Comparison with Nitrendipine in Combination Treatment of Patients with Resistant Essential Hypertension", <i>J of Cardiovascular Pharmacology</i> , 29(suppl 2):S54-S58	
53.	van Zwieten (2000) "The influence of antihypertensive drug treatment on the prevention and regression of left ventricular hypertrophy", <i>Cardiovascular Research</i> , 45:82-91	
54.	Weir AJH (1998) "The Rationale for Combination Versus Single-Entity Therapy in Hypertension", <i>American Journal of Hypertension</i> , 11:163S-169S	

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.

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